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#### INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Application Number	10/099,690			
Filing Date	March 15, 2002			
First Named Inventor	John H. Stevens et al.			
Group Art Unit	3738			
Examiner Name	D. Isabella			
Attorney Docket Number	HRT-293			

	U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No. <sup>1</sup>			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear
70)		3,124,136		Usher	03/1964	
		3,874,388		King et al.	04/1975	
		4,007,743		Blake	02/1977	
		4,061,135		Widran et al.	12/1977	
		4,345,600		Rothfuss	08/1982	
		4,423,730		Gabbay	01/1984	
		4,573,473		Hess	03/1986	
		4,598,698		Siegmund	07/1986	
		4,605,002		Rebuffat	08/1986	
		4,621,638		Silvestrini	11/1986	
		4,628,937		Hess et al.	12/1986	
		4,665,906		Jervis	05/1987	
		4,779,611		Grooters et al.	10/1988	
		4,786,155		Fantone et al.	11/1988	
		4,822,345		Danforth	04/1989	
		4,836,204		Landymore et al.	06/1989	
		4,901,721		Hakki	02/1990	-ULIVER
		4,915,107		Rebuffat et al.	04/1990 <b>/</b> V	ECEIVED DV 1 9 2002
		4,917,089		Sideris	04/1990 TECHNO!	CGY CENTER A3700
		4,943,277		Bolling	07/1990	CENTER Barra
		4,960,424		Grooters	10/1990	10700
		5,029,574		Shimamura et al.	07/1991	
<u>_</u>		5,053,046		Janese	10/1991	
67		5,067,957		Jervis	11/1991	

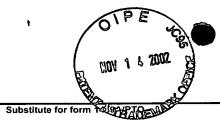
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	5,108,420	Marks	04/1992
6	5,147,374	Fernandez	09/1992
	5,178,133	Pena	01/1993
	5,183,464	Dubrul et al.	02/1993
	5,188,636	Fedotov	02/1993
	5,192,301	Kamiya et al.	03/1993
	5,209,747	Knoepfler .	05/1993
	5,242,457	Akopov et al.	09/1993
	5,275,166	Vaitekunas et al.	01/1994
	5,284,488	Sideris	02/1994
	5,293,869	Edwards et al.	03/1994
	5,295,484	Marcus et al.	03/1994
	5,306,234	W. Dudley Johnson	04/26/1994
	5,309,896	Moll et al.	05/1994
	5,309,910	Edwards et al.	05/1994
	5,312,341	Turi	05/1994
	5,313,943	Houser et al.	05/1994
	5,314,466	Stern et al.	05/1994
	5,318,525	West et al.	06/1994
	5,328,467	Edwards et al.	07/1994
	5,329,927	Gardineer et al.	07/1994
	5,330,492	Haugen	07/1997
	5,334,210	Gainturco	08/1994 RF
	5,334,217	Das	08/1994
	5,336,182	Lundquist et al.	08/1994
	5,338,317	Hasson et al.	08/1994 ECHNOLOGY
	5,345,937	Middleman et al.	09/1994 CENTER PS
	5,346,459	Allen	08/1994 08/1994 09/1994 09/1994
	5,353,783	Nakao et al.	10/1994
	5,358,478	Thompson et al.	10/1994
	5,358,488	Suriyapa	10/1994
	5,361,752	Moll et al.	11/1994
	5,363,861	Edwards et al.	11/1994
	5,364,351	Heinzelman et al.	11/1994
	5,368,592	Stern et al.	11/1994
	5,380,291	Kaali	01/1995
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# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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M	5,381,794	Tei et al.	01/1995	
	5,381,795	Nordgren et al.	01/1995	
	5,383,466	Partika	01/1995	
	5,383,888	Zvenyatsky et al.	01/1995	
	5,386,817	Jones	02/1995	
	5,391,156	Hildwein et al.	02/1995	
	5,397,331	Himpens et al.	03/1995	
	5,400,770	Nakao et al.	03/1995	
	5,402,772	Moll et al.	04/1995	
	5,403,328	Shallman	04/1995	
	5,403,329	Hinchcliffe	04/1995	
	5,405,360	Tovey	04/1995	
	5,409,483	Campbelli et al.	04/1995	
	5,411,481	Allen et al.	05/1995	
	5,421,323	Herrmann et al.	06/1995	
	5,425,357	Moll et al.	06/1995	
	5,425,737	Burbank et al.	06/1995	
	5,425,744	Fagan et al.	06/1995	
	5,425,747	Brotz	06/1995	
	5,433,727	Sideris	07/1995	
	5,450,843	Moll et al.	09/1995	
	5,451,235	Lock et al.	09/1995	Rr.
	5,486,193	Bourne et al.	01/1996	CEllen
	5,507,811	Koike et al.	04/1996	NOVI
	5,613,947	Chin	03/1997 /E	CHIVO! 2002
18	5,924,424	Stevens et al.	07/1999	CENTE
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# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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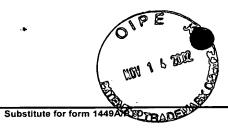
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#### FOREIGN PATENT DOCUMENTS

		Foreign	Patent Docur	nent	Name of Patentee or	Date of Publication of Cited Document	Pages, Columns, Lines, where relevant	
Examiner Cite Initials No.1		Office <sup>3</sup>	Number⁴	KindCode <sup>5</sup>	Applicant of Cited Document	mm-dd-yyyy	passages or relevant figures appear	T <sup>6</sup>
91		EPO	0 573 273	А3		06/1993		
		wo	93/10714			06/1993		
1		wo	93/13712			07/1993		
		wo	94/13211			06/1994		
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		OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS	
		Include name of the author (in CAPITOL LETTERS), title of the article (when appropriate), title of the item	
Examiner's	Cite	(book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s),	T <sup>2</sup>
Initials	No.1	publisher, city and/or country where published	
		Cox et al., "The surgical treatment of atrial fibrillation I. Summary of the Current concepts of the mechanisms of atrial flutter	
70		and atrial fibrillation", J. Thorac Cardivasc Surg 101(2):402-405 (1991)	
		Cox et al., "The surgical treatment of atrial fibrillation II. Intraoperative electrophysiologic mapping and description of the	
		electrophysiologic basis of atrial flutter and atrial fibrillation", J. Thorac Cardiovasc Surg 101(3):406-426 (1991)	
<b>\</b>		Cox et al., "The surgical treatment of atrial fibrillation III. Development of a definitive surgical procedure", J. Thorac Cardiovasc Surg 103(4):569-583 (1991)	
		Cox et al., "The surgical treatment of atrial fibrillation IV. Surgical technique", J Thorac Cardiovasc Surg 101(4):584-592 (1991)	
		Cox et al., "Five-year experience with the Maze procedure for atrial fibrillation", Ann Thorac Surg, 56:814-824 (1993)	
		Das et al., "Experimental atrial septal closure with a new, transcatheter, self-centering device", Circulation 88 [part 1]:1754-1765 (1993)	
		Fishberger et al., "Intraoperative Device Closure of Ventricular Septal Defects", Circulation 88 [part 2]:205-209 (1993)	
		Ganz et al., "Supraventricular Tachycardia", New England J of Med, 332(3):162-173 (1995)	
		Gray et al., "Clinical outcomes and costs of transcatheter as compared with surgical closure of patent ductus arteriosus", 329(21):1517-1523	
		Guffi et al., "Surgical closure of the patent ductus arteriosus with an intravascular prosthesis: Clinical experience", J. Card Surg, 9:343-347 (1994)	
		Hickey et al., "Transcatheter closure of atrial septal defects: Hemodynamic complications and anesthetic management", Anest Analg, 74:44-50 (1992)	_
		Khan et al., "Blade atrial septostomy: Experience with first 50 procedures", Catheterization Cardiovasc Diagn, 23:257-262 (1991)	
		Khan et al., "Experience with 205 procedures of transcatheter closure of ductus arteriosus in 182 patients, with special reference to residual shunts and long-term follow-up", J. Thorac and Cardiovasc Surg., 104(6):1721-1727 (1992)	
		Lock et al., "Transcatheter umbrella closure of congenital heart defects", Circulation 75(3):593-599 (1987)	
		Lock et al., "Transcatheter closure of atrial septal defects - Experimental studies", Circulation, 79:1091-1099 (1989)	
		Lloyd et al., "Atrial septal defect occlusion with buttoned device (a multi-institutional U.S. trial):, Am J Cardiol, 73:286-291 (1994)	
		Mandell et al., "Devices for transcatheter closure of intracardiac defects", AJR, 160:179-184 (1993)	
		Mills et al., "Umbrella catheter for nonoperative closure of artrial septal defects", Medical Instrumentation, 12(1):65-69 (1978)	
		Minich et al., "Echocardiographic guidance during placement of the buttoned double-disk device for atrial septal defect	
<b>/</b> X		closure", Echocardiography, 10(6):567-572 (1993)	
		Aiji dral., "Nonoperative closure of left-to-right shunts", J. Thorac Cardiovasc Surg, 72(3):371-378 (1976)	

Examiner Signature	,	V	7	L	Date Considered /2/(0/1/
		<u></u>	$\Gamma$		



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100	Nykanen et al., "Transcatheter patent ductus arteriosus occlusion: Application in the small child", J Am Coll Cardiol, 23(7):1666-1670 (1994)	
	Park et al., "Clinical use of blade atrial septostomy", Circulation, 58(4):600-606 (1978)	
	Pavcnik et al., "Monodisk: Device for percutaneous transcatheter closure of cardiac septal defects", Cardiovasc Intervent Radiol, 16:308-312 (1993)	
	Rao et al., "Role of 'buttoned' double-disc device in the management of atrial septal defects", Am Heart J, 123(1):191-200 (1992)	
	Rao et al., "Relationship of echocardiographic, shunt flow, and angiographic size to the stretched diameter of the atrial septal defect", Am Heart J., 122:505-508 (1991)	
	Rao et al., "Echocardiographic estimation of balloon - stretched diameter for secundum atrial septal defect for transcatheter occlussion", Am Heart J., 124:172-175 (1992)	
	Rao et al., "Transcatheter closure of atrial septal defect by 'Buttoned" devices", Am J Cardiol, 69:1056-1061 (1992)	
	Redington et al., "Novel uses of the Rashkind ductal umbrella in adults and children with congenital heart disease", Br Heart J, 69:47-51 (1993)	
	Williamson et al., "Radiofrequency catheter modification of atrioventricular conduction to control the ventricular rate during atrial fibrillation", New Engl J Med 331(14):910-917 (1994)	
	Tynan et al., "Transcatheter occlusion of persistent arterial duct:", The Lancet, 340:1062-1066 (1992)	
	Archives of Surgery 9(3)[part II]:689-1066 (1992)	
	van der Velde et al., "Transesophageal echocardiographic guidance of transcatheter ventricular septal defect closure", JACC, 23(7):1660-1665 (1994)	
	Nykanen et al., "Transcatheter patent ductus arteriosus occlusion: Application in the small child", JAAC, 23(7):1666-1670 (1994)	
	Friedman et al., "Successful Closure of a previously unsuspected atrial septal defect by an implantable Clamshell™ Device, and subsequent transvenous pacemaker implantation", Texas Heart J, 21:161-6 (1994)	
	Grifka et al., "New Gianturco-Grifka Vascular Occlusion Device", Circulation, March 15, 91:1840-1846, 1995	
	Pozza et al., "Transcatheter Occlusion fo Patent Ductus Arteriosus Using a Newly Developed Self-Expanding Device", Investigative Radiology, 30(2):104-109, 1995	
	Latson et al., "Endocarditis Risk of the USCI PDA Umbrella for Transcatheter Closure of Patent Ductus Arteriosus", Circulation, 90:2525-2528, 1993	
	Rosenfeld et al., "Echocardiographic Predictors of Candidacy for Successful Transcatheter Atrial Septal Defect Closure", Catheterization Cardiovasc Diagnosis, 34:29-34, 1995	
	Rigby et al., "Primary transcatheter umbrella closure of perimembranous ventricular septal defect", Br Heart J, 72:368-371 (1994)	
	Gray et al., "Examination of the early 'learning curve' for transcatheter closure of patent ductus arteriosus using the Rashkidn occluder", Circulation, 90:II-36-II-42 (Nov. 1994)	
	Laussen et al., "Transcatheter closure of ventricular septal defects: Hemodynamic instability and anesthetic management", Anesth Analg, 80:1076-82 (1995)	
	Reddy et al., "Echocardiographic predictors of success of catheter closure of atrial septal defect with buttoned device", Am Heart J, 129:76-82, Jan 1995	
	Rao et al., "International experience with secundum atrial septal defect occlusion by buttoned device", Am Heart J, 128(5)1022-1035 (Nov. 1994)	
	Galal et al., "Peri-operative complications following surgical closure of atrial septal defect type II in 232 patients - a baseline study", European Heart J, 15:1381-1384 (1994)	
	Pearl et al., "Spontaneous Closure of Fenestrations in an Inteatrial Gore-Tex Patch: Application to the Fontan Procedure", Ann Thorac Surg, 57:611-614 (1994)	
47	Mack et al., "Present Role of Thoracoscopy in the Diagnosis and Treatment of Diseases of the Chest", Ann Thorac Surg., 54:403-409 (1992)	
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